Minutes

Meeting	**Pan Mersey Area Prescribing Committee**
Venue	Microsoft Teams online meeting
Date and time	Wednesday 28 July 2021, 2.00-3.30pm

Members		
AL-JAFFAR, Hannah	Southport and Ormskirk Hospital NHS Trust	Y
ATHERTON, Diane	NHS Wirral CCG	N
AZAR, Mo	Alder Hey Children's NHS Foundation Trust	Y
BARNETT, Rob Dr	Liverpool Local Medical Committee	N
BARTON, Carolyn	NHS Knowsley CCG	Y
CAMPHOR, Ivan	Mid-Mersey Local Medical Committee	N
CARTWRIGHT, Nicola	NHS St Helens CCG	Y
CHARLTON, Marianne	Wirral University Teaching Hospital NHS Foundation Trust	Y
CHILTON, Neil	Mersey Care NHS Foundation Trust	N
COLLINS, Daniel	Liverpool Women's Hospital NHS Foundation Trust	N
CROSBY, John Dr	Mersey Care NHS Foundation Trust	Y
CULLUMBINE, Ann Dr	Wirral Local Medical Committee	Y
DONLON, Kieron	NHS Wirral CCG	Y
DOYLE, Catherine Dr	NHS Warrington CCG	Y
FITZGERALD, Richard Dr	Liverpool University Hospitals NHS Foundation Trust (Royal)	N
FORDE, Claire Dr	NHS Halton CCG	N
FORREST, Danny	Liverpool Heart and Chest Hospital NHS Foundation Trust	N
HAWCUTT, Dan Dr	Alder Hey Children's NHS Foundation Trust	N
HENSHAW, Anne	Midlands and Lancashire Commissioning Support Unit	Y
HUNTER, Anna Dr	NHS South Sefton CCG, NHS Southport and Formby CCG	Y
IRVINE, Adam	Cheshire and Merseyside Local Pharmaceutical Committee	N
ISLAM, Jasmeen	Cheshire and Wirral Partnership NHS FT	N

Members		
JAIN, Adit Dr	NHS Knowsley CCG	N
JOHNSTON, Jenny	NHS South Sefton CCG, NHS Southport and Formby CCG	Y
JOHNSTONE, Peter (Chair)	NHS Liverpool CCG	Y
KNIGHT, Lisa	Wirral Community NHS Foundation Trust	N
LLOYD, Barry	NHS West Lancashire CCG	Y
LUNN, Jenny	NHS Warrington CCG	Y
LYNCH, Susanne	NHS South Sefton CCG, NHS Southport and Formby CCG	N
McKERRELL, Geraldine	Mersey Care NHS Foundation Trust, Community Services Division	Y
McNULTY, Sid Dr	St Helens and Knowsley Teaching Hospitals NHS Trust	Y
MUNYIKA, Agatha	Mersey Care NHS Foundation Trust	Y
PARKER, James	Warrington and Halton Hospitals NHS Foundation Trust	Y
PHILLIPS, Kathryn	Bridgewater Community Healthcare NHS Foundation Trust	Y
PYE, Laura Dr	NHS St Helens CCG	N
RAFFERTY, Sarah	Mersey Care NHS Foundation Trust	N
READE, David Dr	NHS St Helens CCG	N
REID, Lucy	NHS Halton CCG	Y
SANDERSON, Paul	Alder Hey Children's NHS Foundation Trust	N
SKIPPER, Paul	Liverpool University Hospitals NHS Foundation Trust (Royal)	Y
THORNTON, Dave	Liverpool University Hospitals NHS Foundation Trust (Aintree)	Y
THORPE, Bethan	Cheshire and Wirral Partnership NHS FT	N
WELSBY, Mike	St Helens and Knowsley Teaching Hospitals NHS Trust	Y
Non-voting members		
HALL, Gareth	APC lay member	Y
In attendance		
BELLIS, Jenny	Alder Hey Children's NHS Foundation Trust	Y
DINGLE, Helen	Midlands and Lancashire CSU	Y
MARSDEN, Ashley	North West Medicines Information Centre	Y
READER, Graham	Midlands and Lancashire Commissioning Support Unit	Y
WILSON, Paula	Midlands and Lancashire Commissioning Support Unit	Y

1	**Welcome and apologies**	
	The Chair welcomed members. Apologies were accepted from: Dr Richard Fitzgerald, John Williams (Hannah Al-Jaffar attending), Susanne Lynch (Jenny Johnston attending), Dr Nick Cross, Dr Adit Jain, Neil Chilton, Dr Claire Forde, Dr Laura Pye, and Ifeoma Onyia.	
2	**Declarations of interest and quoracy**	
	A quoracy check confirmed that this meeting was not quorate. There were two declarations of interest for item 8.1 on the agenda: AHu - commissioned to provide a primary care led transgender service for South Sefton and Southport & Formby CCGs. Also working on a consultancy basis for CMAGIC, as a locum contractor, but has not undertaken any work for the service yet. JC - Medical Director for Mersey Care, which is the organisation that hosts CMAGIC, but does not work directly for the service. The Chair advised the committee that both AHu and JC could provide valuable input into discussions for item 8.1 and so should be allowed to participate fully in discussions and in the usual APC 'show of hands' used to establish members' agreement with the APC recommendation, as this does not constitute a formal vote.	
3	**Minutes of the last meeting**	
	The Minutes of the APC meeting on 23 June 2021 could not be formally ratified as the meeting was not quorate so they will be brought back to the next meeting.	
4	**Matters arising**	
4.1	**APC finance representative** Last year it was agreed that AH would explore the possibility of appointing a finance representative on to the Area Prescribing Committee. The Directors of Finance were really supportive of the idea but have requested that this is paused until there is more clarity regarding the roles in finance in the ICS. AH will pick this up again in January 2022, with a view to hopefully appointing a finance representative for the new financial year in April 2022.	
5	**New medicines**	
5.1	**Grey statement summary** The following grey 'holding' statement has been produced for the APC website: INCLISIRAN solution for injection (Leqvio ®▼): For the treatment of primary hypercholesterolaemia or mixed dyslipidaemia. This will be reviewed when the NICE TA is published (date TBC). This was noted and approved by the APC.	

5.2	**Expiry extension – sodium oxybate and pitolisant for narcolepsy** Red policy statements for sodium oxybate and pitolisant for the treatment of narcolepsy were approved by APC in March 2019, along with the accompanying narcolepsy pathway. The policy statements were given a 2 year expiry (March 2021) and the pathway a 3 year expiry (March 2022), as per agreed convention for APC documents. The NMSG proposes that the expiry of the red statements for both sodium oxybate and pitolisant should be extended to March 2022 to bring them in line with the narcolepsy pathway expiry date. The NMSG is of the opinion there is currently no new information that would change the position of sodium oxybate and/or pitolisant. There is a further new drug expected to be launched and reviewed by NICE during this time, and therefore extending the expiry allows all three drugs and the pathway to be reviewed simultaneously and avoid duplication of effort. The APC approved the expiry extension from March 2021 to March 2022 for the sodium oxybate and pitolisant red statements.	
5.3	**Dapagliflozin for symptomatic chronic heart failure with reduced ejection fraction – appeal against APC RAG status** NICE TA679 was published in February and an amber initiated statement was approved by APC on 24 March 2021. The NMSG proposed amber initiated RAG was on the grounds of the need for counselling patients regarding DKA and co-ordinating heart failure and diabetes care when initiating treatment. An email was received on 07 April 2021 stating a case for appeal against the amber initiated RAG and a completed appeal form was received on 14 May 2021 and the appeal accepted. The grounds for appeal against the RAG rating are that NICE TA679 states: “Start treatment of symptomatic heart failure with reduced ejection fraction with dapagliflozin on the advice of a heart failure specialist” and so the requirement for the specialist to initiate and stabilise treatment with dapagliflozin was considered to put additional barriers in place that restrict patient access to a NICE TA drug. The NMSG were asked to review the RAG status in light of the appeal and concluded that it is within GP competence to initiate prescribing of dapagliflozin for heart failure, provided the specialist identified the patient as a suitable candidate for dapagliflozin treatment. There was considerable discussion over who should counsel the patients regarding the risk of DKA with dapagliflozin. The NMSG agreed that the recommending specialist should counsel the patient as part of the shared decision to initiate treatment. However, the clinician who initiates prescribing is ultimately responsible for ensuring that the patient has received appropriate counselling as part of their overall responsibility when prescribing any drug. Stakeholder feedback from primary care was mixed and there were some reservations about the change from amber initiated to amber recommended. However, the NMSG felt that amber initiated could be seen to create additional barriers to patient access to treatment. It was agreed that an algorithm and patient leaflets would help to support primary care clinicians initiate prescribing after specialist recommendation. However, these could not be produced and consulted on within the 90-day timescale for the appeal to be concluded. Therefore, these are being developed and will be brought to APC at a	

	later date. The APC was asked to consider the grounds for appeal, the stakeholder feedback and whether to approve a change to amber recommended RAG. The APC discussed at length and there were still considerable concerns around patient safety, especially around DKA, counselling of patients and multidisciplinary working to co-ordinate heart failure and diabetes care, from both primary and secondary care representatives. It was raised that other local APCs have approved in line with the NICE TA wording and so this is restricting access for patients in Pan Mersey and is an equity issue that will be challenged. However, the committee were of the opinion that patient safety was the primary concern and that the amber initiated RAG is safer for patients. The committee agreed that, because the meeting was not quorate, the change from amber initiated to amber recommended RAG could not currently be implemented and a final APC decision on the matter would need to be deferred. There were still considerable concerns around patient safety, from both primary care and secondary care clinicians, that could not be addressed within the standard timescales for responding to the appeal. It was agreed that further work needed to be undertaken with the heart failure specialists regarding how they co-ordinate the necessary multidisciplinary input for patients with both heart failure and type 2 diabetes. Further discussion will need to take place at the Chief Pharmacists' and CCG Leads' meeting on 11th August regarding how this can be taken forward, and the New Medicines Subgroup will continue to work on the treatment algorithm and patient leaflets. The committee acknowledged that an amber initiated RAG could be considered to be putting additional barriers in the way of patients accessing treatment compared to the wording within the NICE TA, however they were of the opinion that this position needed to be maintained on patient safety grounds. The appellant will be informed of the outcome of today's meeting and advised that the appeal was not upheld at this point, but further work will be undertaken regarding the safe implementation of NICE TA679.	Chiefs/ Leads AH/PJ
5.4	**Budesonide for inducing remission of eosinophilic oesophagitis – NICE TA708** Red statement in line with NICE TA708 that recommends budesonide orodispersible tablet (Jorveza®▼) as a treatment option for inducing remission of eosinophilic oesophagitis in adults, with a treatment course of up to 12 weeks. Prescribing must be initiated and retained by the gastroenterology specialist. The TA recommendation does not extend to maintenance of eosinophilic oesophagitis as the company only submitted evidence for inducing remission. NICE do not expect this guidance to have a significant impact on resources because the overall cost of treatment is low and eosinophilic oesophagitis is a rare condition. The red statement was approved by the APC.	
5.5	**Guselkumab for psoriatic arthritis – NICE TA711** Red statement in line with NICE TA711 that recommends guselkumab, alone or with methotrexate, as an option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them, only if certain criteria are met.	

	Guselkumab must be provided in accordance with the commercial arrangement, and prescribing and monitoring must be retained by a specialist in the management of psoriatic arthritis. NICE does not expect this guidance to have a significant impact on resources because guselkumab is a further treatment option available at a similar price to the current treatment options. The APC approved the red statement.	
5.6	**Biologic agents for moderate rheumatoid arthritis – NICE TA715** Red statement in line with NICE TA715 that recommends adalimumab, etanercept and infliximab, all with methotrexate, as options for treating moderate rheumatoid arthritis (DAS28 of 3.5-5.1) if intensive therapy with two or more conventional DMARDs has not controlled the disease well enough. Adalimumab and etanercept can be used as monotherapy when methotrexate is contraindicated or not tolerated. Treatment should be continued only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy, and response is maintained. Drugs must be provided at the same or lower prices than those agreed with the Commercial Medicines Unit, with prescribing and monitoring retained by the specialist. Abatacept is not recommended for the treatment of moderate RA. Currently only filgotinib is NICE TA approved for the treatment of moderate RA. This is a significant cohort of patients for whom there is an unmet clinical need. NICE estimates the additional resource impact of implementing this guidance as £28,000 per 100,000 population in 2021/22, rising to £67,000 per 100,000 in 2023/24, when steady state is assumed to have been reached. The APC confirmed their approval of the red statement.	
6	**Formulary and Guidelines**	
6.1	**Pan Mersey Prescribing Guidelines for Specialist Infant Formula Feeds in Lactose Intolerance and Cows' Milk Protein Allergy** This is a routine update of the current Pan Mersey guideline. Referral pathways have been re-written, along with information about local access to feeding clinics and specialist dieticians, to reflect the variation across the Pan Mersey region. Consultation feedback comments have been addressed. The APC confirmed their agreement to the guideline and CCGs confirmed that their existing approvals can be carried over.	
6.2	**Dulaglutide 3mg, 4.5mg injection** The FGSG proposes the addition of dulaglutide injection (pre-filled pen) 3mg and 4.5mg to formulary section 6.1.2.3, designation green. The doses currently approved by Pan Mersey are 0.75mg or 1.5mg, weekly. Higher doses offer greater glucose lowering and weight loss efficacy compared with dulaglutide 1.5 mg weekly (as demonstrated in the AWARD-11 study). Cost is the same as 0.75mg	

	and 1.5mg (£73.25 per 4 pens). It was confirmed that dulaglutide is not indicated for weight management. The APC agreed to this addition to formulary.	
6.3	**Expiry extension of Pan Mersey document – Flash Glucose Monitor** The FGSG proposes that the Flash Glucose Monitor (FreeStyle Libre® / Libre 2®) document with a review-by date of July 2021, could be considered for an extension to its review-by date until March 2022 as major changes are thought to be unlikely. This would be reviewed sooner should significant developments occur. This expiry date extension to March 2022 was agreed.	
7	**Antimicrobials**	
7.1	**Suspected meningococcal disease** The APC was asked to approve an updated recommendation that now emphasises urgent hospital transfer. Benzylpenicillin is recommended in all cases except for people with a history of anaphylaxis following penicillin treatment. A history of rash is not a contraindication and cefotaxime has been removed as an alternative since it would not be an appropriate choice where anaphylaxis is a concern. Consultation feedback was broadly positive. It was noted that IV access in primary care is difficult, but the guidance offers IM as an alternative. There were no changes to define what is a contraindication to penicillin, the review group consensus was the advice to withhold benzylpenicillin was clear. The APC confirmed their approval.	
8	**Shared Care**	
8.1	**Cheshire and Merseyside Gender Identity Collaborative (CMAGIC). Prescribing support information for oestradiol, testosterone and gonadorelin analogues** New prescribing support information for oestradiol, testosterone and gonadorelin analogues has been written to support prescribing for patients attending the Cheshire and Merseyside Gender Identity Collaborative (CMAGIC) which is newly established and is hosted by Mersey Care NHS Foundation Trust. It will also provide support for GPs who are already prescribing treatment for gender incongruence. The RAG rating is amber initiated for oestradiol and testosterone and amber retained for gonadorelin analogues. Oestrogen treatment for feminisation and testosterone treatment for masculinisation are lifelong. Gonadorelin analogue treatment would be added when required to support oestrogen or testosterone for transition either way and only until gonadectomy. CMAGIC will have a prescribing budget and prescribe for the first 6 or 12 months until the dose and monitoring are stable, and the patient only requires annual monitoring. Some consultation feedback from CCGs suggested the RAG rating should be purple or amber retained. CMAGIC was very keen for the RAG rating to be amber initiated for oestradiol and testosterone. The initial period of prescribing and monitoring will be done by the service to support this RAG rating. There is an option for the GP to fast track the	

	patient back to the gender service at any time and patients will be seen at regular intervals to monitor their wellbeing and progress. There was a suggestion that monitoring recommendations should be clarified, and this has been done. One clinician expressed concern that the prescribing and monitoring is retained by the service for 6-12 months, but this timescale was agreed with CMAGIC as the best way to assist with the uptake of the guidance with an amber initiated RAG rating. AHu explained the background to CMAGIC. Waiting times for the initial assessment for this cohort of patients is about 3-5 years and NHSE, in trying to resolve this, have commissioned 3 services nationally, of which CMAGIC is one. JC advised that the mental health problems and self-harm rates in this group of patients are significant, and this is the reason Mersey Care is hosting the service. The APC approved these three prescribing support documents.	
8.2	**Low molecular weight heparin (LMWH) prescribing support information** A routine review of the patient support information and the GP letter has been carried out. HD outlined the amendments/additions made to the monitoring arrangements and specialist responsibilities. The updated documents were agreed, and the CCG approvals will be carried over.	
9	**APC reports**	
9.1	**APC annual report 2020/21** The annual report up to the end of March 2021 was presented. Covid-19 has impacted on the APC and its outcomes, but the APC has adapted well throughout the year. There were no comments or questions. The APC Report was approved and will be uploaded to the website.	
9.2	**NICE TA Adherence Checklist (June 2021) – for noting** Pan Mersey APC is compliant up to the end of June 2021. The report will be uploaded to the APC website.	
9.3	**RMOC update** The national work on shared care frameworks is ongoing. The RMOC documents are being sent out for consultation separately from the APC documents and the Shared Care Subgroup is responding to consultations on behalf of the APC, although individual comments are still invited. RMOC North has been scheduled to meet next online, in September. Following that meeting, AH will give a further update to the committee at the September APC meeting.	
10	**Any other business**	
10.1	**Mersey Care and North West Boroughs** Following the recent merger to form one organisation, JC raised the issue of too many voting members on the APC. It was agreed that JC will contact AH to discuss this matter further once the D & T committees of both organisations have merged.	

10.2	**APC Chair** The 12-month tenure comes to an end soon so members were asked to submit nominations to be considered for APC Chair, to AH by 10th September 2021 so that this can be progressed at the September APC meeting.	All
11	**Next meeting**	
	Wednesday 22 September 2021 at 2.00pm to TBC. Online meeting via Microsoft Teams.	